APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,478	03/01/2004	Shoupu Chen	86570SLP	9531

70523   7590   12/10/2007
Carestream Health Inc,
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EXAMINER
PARK, EDWARD

ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/790,478	CHEN ET AL.
	Examiner	**Art Unit**	
	Edward Park	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1.   A request for continued examination under 37 CFR 1.114, including the fee set forth in

37 CFR 1.17(e), was filed in this application after final rejection. Since this application is

eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e)

has been timely paid, the finality of the previous Office action has been withdrawn pursuant to

37 CFR 1.114. Applicant's submission filed on 11/27/07 has been entered.

Claim Objections

2.   In response to applicant's amendment of claim 15, received on 11/27/07, the previous

claim objection is withdrawn.

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

4.   **Claims 1-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al.

(US 6,951,536 B2) with Alfano et al (US 6,240,312 B1), and further in view of Nemeth et al.

(WO 01/99703 A2).

Regarding **claims 1 and 11**, Yokoi teaches an automatic notification and remote access

method for diagnosing real-time in vivo images from a location remote from one or more in vivo

video camera systems, comprising the steps of:

a) capturing multiple sets of real-time in vivo images ("set of images captured inside the

body"; Yokoi: col. 19, line 63-64) using the one or more in vivo video camera systems ("an

image pickup device and an illumination device"; Yokoi: figure 4; col. 4, lines 65-67);

Yokoi does not teach forming an examination bundlette, image processing the

examination bundlette; automatically detecting one or more abnormalities in the examination

bundlette, signaling an alarm, receiving an automatic notification, routing the automatic

notification to remote recipient(s), executing one or more diagnosing tasks and applying image

processing algorithms to an image portion of the examination bundlette.

Alfano teaches image processing the examination bundlette and applying image

processing algorithms to an image portion of the examination bundlette (see figure 1; col. 6, lines

21-35).

It would have been obvious at the time the invention was made to one of ordinary skill in

the art to modify the Yokoi reference to image process/processing algorithms to the examination

bundlette as suggested by Alfano, in order "to improve the sensitivity of the disease diagnosis"

(Alfano: col. 6, lines 21-35).

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

b) forming an in vivo video camera system examination bundlette of a patient that includes the real-time ("real time"; Nemeth: pg. 9, line 20) captured in vivo images for each of the one or more in vivo video camera systems ("medical data relating to physiological or biological status of a patient includes all data relating to the physical condition and composition of the patient"; Nemeth: figure 1, numeral 10; pg. 14, lines 19-21). Images fall under the category of medical data since it is well known in the art that data transcribed in the form of medical images are essential for examination purposes.

d) automatically detecting one or more abnormalities in one or more of the in vivo images in the examination bundlette ("analyze the medical data to determine if any of the conditions under which an alert is to be provided"; Nemeth: figure 2, numeral 58; pg. 22, lines 20-28);

e) signaling an alarm provided that the one or more abnormalities in the examination bundlette have been detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18);

f) receiving an automatic notification via one or more unscheduled alarming messages from one or more randomly located in vivo video camera systems "store the medical data and other related information for review by third party" (Nemeth: figure 2, numeral 64);

g) routing the automatic notification to remote recipient(s) ("other parties can be notified in the same or a different manner"; Nemeth: figure 2, numeral 68, pg. 11, lines 5-12); and

h) executing one or more diagnosing tasks corresponding to the automatic notification ("third party may instruct the patient to take certain remedial measures"; Nemeth: figure 2, numeral 70; pg. 27, lines 30-32; pg. 28, lines 1-16).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Alfano combination as mentioned above to utilize forming an in vivo video camera system examination bundlette as suggested by Nemeth, in order to further enhance the treatment of a patient by allowing all data to be accessible at once by any party.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Alfano combination to automatically detect one or more abnormalities in the examination bundlette based on predetermined criteria for the patient as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi with Alfano combination to signal, receive, and route an alarm/message, and to execute one or more diagnosing tasks as suggested by Nemeth, in order to allow "the third party to quickly review the medical data and other related information, to provide instructions for any necessary remedial action" (Nemeth: pg. 33, lines 3-5) and to effectively treat the patient's illness or ailment.

Regarding **claim 2**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the unscheduled alarming messages correspond to a detection ("conducting examination"; Yokoi: col. 2, lines 5-7) of an abnormality found in the patient's GI tract ("inside of somatic cavities"; Yokoi: figure 1, numeral 16A, B; col. 2, lines 5-7).

Regarding **claim 3**, the Yokoi, Alfano, with Nemeth combination teaches the elements disclosed in claim 1. The Yokoi, Alfano, with Nemeth combination as mentioned above in claim 1, does not teach where in the automatic notification includes patient metadata describing the patient's medical history and location. Nemeth further teaches where in the automatic notification includes patient metadata describing the patient's medical history and location ("position of the patient .... underlying medical data"; Nemeth: pg. 10, lines 5-15). It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Alfano, with Nemeth combination to include patient metadata describing the patient's medical history and location as suggested by Nemeth, in order to have all related patient information bound together to effectively treat the patient's illness or ailment.

Regarding **claim 4**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the one or more randomly located in vivo video camera systems are located in different geographic regions of a country and/or a continent ("patient is in a remote location far from a hospital"; Yokoi: fig. 36A, B; col. 25, lines 20-31).

Regarding **claim 5**, the Yokoi, Alfano, with Nemeth combination teaches the elements disclosed in claim 1. The combination does not teach providing a communication channel and providing the remote recipient(s) with the automatic notification of a detected GI tract abnormality. Nemeth further teaches wherein the step of routing the automatic notification to the remote recipient(s), further comprises the steps of:

providing a communication channel to the remote recipient(s) ("medical data is transmitted via the internet such that the third party can view the medical data"; Nemeth: pg. 10, lines 24-25); and

providing the remote recipient(s) with the automatic notification of a detected GI tract abnormality ("transmit an alert if it is determined that the medical data meets the conditions established for the generation of an alert"; Nemeth: pg. 10, lines 29-31).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Alfano, with Nemeth combination to provide a communication channel and automatic notification as taught by Nemeth, in order to allow "the third party to quickly review the medical data and other related information, to provide instructions for any necessary remedial action" (Nemeth: pg. 33, lines 3-5) and to effectively treat the patient's illness or ailment.

Regarding **claim 6**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the unscheduled alarming messages operate within a two-way messaging system ("cellular phones, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 38-39).

Regarding **claim 7**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the remote recipient receives messages by utilizing a two-way messaging system ("cellular phones, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 38-39).

Regarding **claim 8**, the rejection of claim 1 is incorporated and Yokoi further discloses wherein the remote access is accomplished by a communications network ("transmission may be conducted with other communications means such as cellular phone, internet"; Yokoi: fig. 36A, numeral 182; col. 25, lines 9-13, 35-39) for retrieving and/or sending the patient's in vivo images from multiple locations either inside or outside ("remote site"; Yokoi: col. 25, lines 9-13, 35-39) of a clinical environment ("remote location far from a hospital"; Yokoi: col. 25, lines 9-13, 35-39).

Regarding **claim 9**, the rejection of claim 1 is incorporated and Yokoi further discloses

wherein the step of forming the examination bundlette, includes the steps of:

forming an image packet of the captured in vivo images of the patient ("image data ...

accumulated in memory"; Yokoi: col. 22, lines 11-13);

forming patient metadata ("memory storing the patient's data"; Yokoi: col. 22, lines 21);

and

combining the image packet and the patient metadata into the examination bundlette

("when the image data are transmitted, the patient's data stored in the memory may be

transmitted as header information of the image data"; Yokoi: col. 22, lines 20-25).

Regarding **claim 10**, the rejection of claim 1 is incorporated and Yokoi further discloses

wherein the step of processing the examination bundlette, includes the steps of:

separating the in vivo images from the examination bundlette ("identification code may

be recognized by the external unit and separated from the image data" Yokoi: col. 20, lines 43-

44);

and processing the in vivo images according to selected image processing methods

("control circuit ... conducts a comparative processing such as pattern matching of the captured

image and the disease image read out from the disease database ..."; Yokoi: figure 18; col. 19,

lines 29-35).

5.   **Claims 12-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al.

(US 6,951,536 B2), Alfano et al (US 6,240,312 B1), with Nemeth et al. (WO 01/99703 A2), and

further in view of Kenet et al (US 5,836,872).

Regarding **claims 12-15**, Yokoi, Alfano, with Nemeth combination discloses all elements as mentioned above in claim 1. The Yokoi, Alfano, with Nemeth combination does not teach detecting one or more abnormalities based on predetermined image criteria for the patient; detecting one or more abnormalities based on predetermine image criteria for the patient employing image data transformation and detection; transforming image data for an image portion of the examination bundlette to a generalized color space; detecting one or more abnormalities by applying thresholding; and applying lower/higher thresholding or higher thresholding.

Kenet teaches detecting one or more abnormalities based on predetermined image criteria for the patient (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); detecting one or more abnormalities based on predetermine image criteria for the patient employing image data transformation and detection (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); transforming image data for an image portion of the examination bundlette to a generalized color space (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); detecting one or more abnormalities by applying thresholding (Kenet: col. 16, lines 36-67; col. 17, lines 1-15); and applying lower and higher thresholding or higher thresholding (Kenet: col. 16, lines 36-67; col. 17, lines 1-15).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi, Alfano, with Nemeth combination to utilize image transformation and to detect abnormalities through thresholding as suggested by Kenet, in order to enhance the reliability, precision of the system in regards to detection of abnormalities.

6.   **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2) in view of Nemeth et al. (WO 01/99703 A2).

Regarding **claim 16**, Yokoi discloses a method comprising:

capturing a real-time in vivo image ("set of images captured inside the body"; Yokoi: col. 19, line 63-64);

Yokoi does not disclose automatically detecting an abnormality in real-time in the in vivo image; and signaling an alarm in real-time when the abnormality is detected.

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

automatically detecting an abnormality in real-time in the in vivo image ("analyze the medical data to determine if any of the conditions under which an alert is to be provided"; Nemeth: figure 2, numeral 58; pg. 22, lines 20-28);

signaling an alarm in real-time when the abnormality is detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; "provide alerts, warnings and other information to third party will be informed, preferably in real time or near real time, of instances which the medical data meet certain predetermined conditions that merit the immediate attention of the third party; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18; pg. 7, lines 24-28).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi reference to automatically detect an abnormality and signal an alarm as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

7.   **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (US 6,951,536 B2) with Nemeth et al. (WO 01/99703 A2), and further in view of Li et al (US 6,470,092 B1).

Yokoi discloses a method, comprising:

capturing a real-time in vivo image ("set of images captured inside the body"; Yokoi: col. 19, line 63-64);

Yokoi does not disclose automatically detecting an abnormality in real-time in the in vivo image by comparing the image to abnormality feature templates; and signaling an alarm in real-time when the abnormality is detected.

Nemeth, in the same field of "monitoring medical data" (Nemeth: pg. 1) teaches:

automatically detecting an abnormality in real-time in the in vivo image ("analyze the medical data to determine if any of the conditions under which an alert is to be provided"; Nemeth: figure 2, numeral 58; pg. 22, lines 20-28);

and signaling an alarm in real-time when the abnormality is detected ("analyze the medical data and provide the third party with an alert if the medical data meets the established conditions for an alert"; "provide alerts, warnings and other information to third party will be informed, preferably in real time or near real time, of instances which the medical data meet certain predetermined conditions that merit the immediate attention of the third party; Nemeth: figure 2, numeral 58; pg. 32, lines 17-18; pg. 7, lines 24-28).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Yokoi reference to automatically detect an abnormality and signal an alarm as suggested by Nemeth, in order "analyze and respond to the medical data in a timely matter" (Nemeth: pg. 8, lines 11) and to reduce human errors in manual detection.

Li, in the same field of medical abnormality detection in images (see col. 1, lines 15-18) teaches detecting an abnormality by comparing the image to abnormality feature templates (see

col. 2, lines 3-28 obtaining templates and comparing the candidate abnormality with the

templates).

It would have been obvious at the time the invention was made to one of ordinary skill in

the art to modify the Yokoi with Nemeth combination to compare an image to abnormality

feature templates as suggested by Li, to determine a "cross-correlation value" to determine

whether an abnormality is malignant or benign (col. 2, lines 3-28).

Response to Arguments

8.   Applicant's arguments filed on 11/27/07 with respect to **claim 1** have been fully

considered but they are not persuasive. Applicant argues that the references do not disclose data

being normal or abnormal. This argument is not considered persuasive since Nemeth teaches

abnormal medical data which triggers an alert to a third party (Nemeth: pg. 22, lines 6-31).

Furthermore, the applicant argues that the limitations of claim 1 are not met. This argument is

not considered persuasive and the rejection of claim 1 can be seen above.

In regards to **claims 12-15**, applicant argues that Kenet does not add anything to the

features of the invention discussed above. Applicant's arguments fail to comply with 37

CFR 1.111(b) because they amount to a general allegation that the claims define a patentable

invention without specifically pointing out how the language of the claims patentably

distinguishes them from the references. Therefore, this applicant argument is not considered
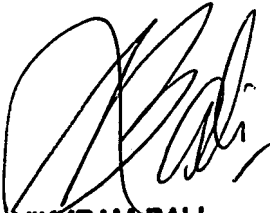
persuasive.

Conclusion

9.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Park whose telephone number is (571) 270-1576. The examiner can normally be reached on M-F 10:30 - 20:00, (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on (571) 272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

<div style="text-align: right">

Edward Park
Examiner
Art Unit 2624

</div>

/Edward Park/

VIKKRAM BALI
PRIMARY EXAMINER